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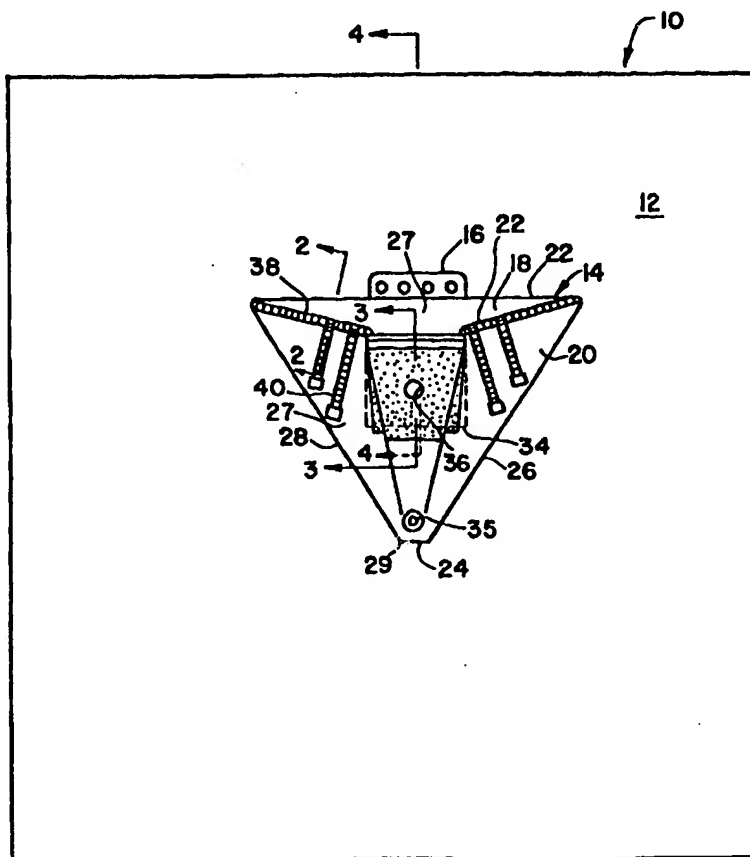


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/US96/13228 <b>(22) International Filing Date:</b> 16 August 1996 (16.08.96) <b>(30) Priority Data:</b> 60/003,237 5 September 1995 (05.09.95) US 08/655,538 30 May 1996 (30.05.96) US <b>(71) Applicant:</b> KIMBERLY-CLARK WORLDWIDE, INC. [US/US]; 401 North Lake Street, Neenah, WI 54956 (US). <b>(72) Inventors:</b> DOWDY, Richard, C.; 11145 Crofton Overlook Court, Duluth, GA 30136 (US). BERGSBAKEN, Brad, S.; 4510 West Joshua Lane, Tuscon, AZ 85741 (US). <b>(74) Agents:</b> HARPS, Joseph, P. et al.; Kimberly-Clark Worldwide, Inc., 401 North Lake Street, Neenah, WI 54956 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>

**(54) Title:** SURGICAL DRAPE AND METHOD OF ASSEMBLY**(57) Abstract**

A surgical drape having a liquid collection pouch is provided. The liquid collection pouch includes support structures secured thereto along and boarding the mouth of the liquid collection pouch and along the side walls of the liquid collection pouch. Examples of the support structures include malleable strips, malleable coated strips, malleable wire, malleable coated wire, plastic and foam rods or any combination thereof.



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SURGICAL DRAPE AND METHOD OF ASSEMBLY

5

FIELD OF INVENTION

The present invention relates to surgical drapes and more particularly, to surgical drapes having liquid collection pouches secured thereto.

10

BACKGROUND OF THE INVENTION

As is generally known, sterile surgical drapes can be designed to greatly reduce, if not prevent, the transmission through the draping material of liquids and biological contaminants which may become entrained therein. In such surgical procedure environments, liquid and biological contaminants include, for example, operating room personnel perspiration, patient liquids, such as blood, and life support liquids, such as plasma and saline.

In the past, reusable surgical drapes were made of cotton or linen and were sterilized prior to use in the operating room. These materials however permitted transmission or "strike-through" of various liquids encountered in surgical procedures. In these instances, a path was established for transmission of bacteria and other contaminants to and from the patient.

Disposable surgical drapes, which are also sterilized prior to use in the operating room, have largely replaced the reusable surgical drapes, such as linen and cotton surgical drapes. Many disposable surgical drapes are customized to be compatible with specific procedures such as neurological, obstetric, orthopedic, cardiovascular and ophthalmic procedures. Several procedures, and particularly arthroscopic surgical procedures, generate considerable quantities of liquids during the course of the surgical procedures. Such liquids generated during such

surgical procedures include, for example, blood, saline and irrigation fluids.

In an effort to contain these liquids, liquid collection pouches are generally secured to the surgical drape fabric near the operative site to collect such liquids. However, for the liquid collection pouches to successfully collect these liquids, the mouth of the liquid collection pouches must remain in an open, liquid receiving position. Traditionally, materials which have been incorporated into the design of these liquid collection pouches to maintain the mouth of the pouches in an open position include, for example, malleable-coated wire or rods and foam strips or rods. Generally, these malleable-coated wires or foam strips are secured about and encircle a portion of the mouth of the liquid collection pouch. Additionally, many such liquid collection pouches are provided with liquid drainage ports.

However, it is desirable that these liquid collection pouches not only remain in an open, a liquid receiving position at the beginning of a surgical procedure, but that these pouches remain open during the entire surgical procedure. It is common during the course of a surgical procedure for considerable quantities of surgical liquids to be generated. And, while many such liquid collection pouches are equipped with liquid drainage ports, in many instances, either because of blockage of the drainage ports or the fact that the drainage ports are not connected to a liquid evacuation system, considerable quantities of such liquids may collect in the liquid collection pouches. In these instances, the weight of these collected liquids may cause the openings of these liquid collection pouches to partially close or collapse.

Additionally, as many surgical drapes are intended for a single use, the design of these surgical drapes, and the materials incorporated therein must also be suited for low cost manufacturing such that discarding the surgical drape after only a single use is economical.

Therefore there exists a need for a surgical drape having a liquid collection pouch which will resist the tendency to close as the volume of liquid contained therein increases. There also exists a need for a surgical drape  
5 having a liquid collection pouch which is economical to manufacture.

### Summary of the Invention

10 In response to the above need for a surgical drape having a liquid collection pouch which will resist the tendency to close as the volume of liquid contained therein increases, the present invention provides a liquid collection pouch having support structures secured thereto  
15 not only along and bordering the mouth or opening of the liquid collection pouch but also along the side walls of the liquid collection pouch. Desirably, the liquid collection pouch is secured to the main sheet of a surgical drape.

20 The liquid collection pouch of the present invention includes continuous side walls closed at one end and open at the other end. A first support structure is secured to the side walls adjacent the opening and extending for a distance along said opening. A second support structure,  
25 secured to the side walls, extends generally in a direction from the opening of the liquid collection pouch to the closed end of the liquid collection pouch.

In another embodiment, a generally laterally oriented support structure may be secured to the side walls adjacent  
30 the opening in the liquid collection pouch such that the laterally oriented support structure extends for a distance along said opening. The liquid collection pouch may further include a generally vertically oriented support structure secured to the side walls. The liquid collection pouch may  
35 also include an opening in the side walls, and an elastic panel secured to said side walls such that the elastic panel overlies the wall opening.

In another embodiment, the present invention provides a surgical drape which includes a main sheet having an opening therein and a liquid collection pouch. The liquid collection pouch includes a pair of juxtaposed panels. The pair of juxtaposed panels are united along a portion of their overlying edges such that a liquid collection pouch opening is formed. Each panel has portions defining an opening. An elastic panel is secured to each panel such that the elastic panel overlies the opening. Each elastic panel has portions defining an expandable opening adapted for receiving a body part. A first length of malleable coated wire is secured adjacent one of the edges of one of the panels which defines the liquid collection pouch opening such that said first length extends for a distance along the liquid collection pouch opening. A plurality of spaced apart lengths of malleable coated wire are secured to the same panel to which the first length of malleable coated wire is secured. The plurality of spaced apart lengths of malleable coated wire extend generally vertically from the liquid collection pouch opening when the liquid collection pouch is in an open position. The other panel is secured to the main sheet such that the expandable opening of the elastic panel overlies the opening in the main sheet.

25

#### Brief Description of the Drawings

FIG. 1 is a plan view of a surgical drape illustrating a liquid collection pouch secured to the main sheet of the surgical drape.

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FIG. 2 is a cross-sectional view taken along line 2-2 in FIG. 1.

FIG. 3 is a cross-sectional view taken along line 3-3 in FIG. 1.

FIG. 4 is a cross-sectional view taken along line 4-4 in FIG. 1.

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FIG. 5 is a perspective view of the liquid collection pouch illustrated in FIG. 1.

Detailed Description of the Present Invention

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Several terms are used herein to refer to attaching or securing one or more parts of the drape or the liquid collection pouch to another part of the drape or pouch. Such attaching or securing such parts to one another may be accomplished by several conventional methods. By way of example and not limitation, these methods include zipping, snapping, taping, using matingly engaging hook and loop fasteners, such as VELCRO®, buttons, cohesive adhesives, adhesives, hot melt adhesive, stitching, gluing, heat sealing, sonic or thermal bonding and other methods familiar to those skilled in the art.

Turning now to drawings and with reference to FIG. 1, the surgical drape of the present invention is indicated by the reference numeral 10. The surgical drape 10 includes a main sheet 12 and a liquid collection pouch 14 which is secured to the main sheet 12. The main sheet 12 includes portions defining an opening 13 (FIG. 4), which will be described in greater detail below. A tube holder 16 having a plurality of openings therein for receiving tubes is secured to the main sheet 12.

The drape design 10 illustrated in FIG. 1 will generally be recognized by one skilled in the art as an arthroscopic drape or a drape suitable for use in performing arthroscopic procedures. It will be understood by those skilled in the art that the present invention is equally applicable for use in a plurality other surgical procedures which require drape designs which may differ from the design of drape 10. By way of example and not limitation, other drape designs for other surgical procedures requiring a drape design different from the design illustrated in FIG. 1 include a lap-chole drape, a thyroid drape and a laparoscopy drape.

The main sheet 12 and the tube holder 16 may be made from a multitude of disposable and/or reusable materials. Examples of suitable reusable materials include, but are not limited to, cotton, linen, polyester, woven polyester and polytetrafluoroethylene. A generally disposable material well-suited for use in forming the main sheet 12 and/or the tube holder 16 is a three-layer nonwoven polypropylene material known as SMS. SMS is an acronym for spunbond, meltblown, spunbond. See for example, U.S. Patent No. 4,041,203 to Brock et al. One particular advantage is that the SMS material exhibits enhanced liquid barrier characteristics. It should be noted, however, that other disposable nonwovens as well as other materials including wovens, films, foam/film laminates and combinations thereof may be used in the present invention. It is also contemplated that the main sheet 12 may be coated with a liquid impervious coating to prevent liquid absorption.

Referring now to FIG.s 1 and 5, the liquid collection pouch 14 is formed from a pair of panels 18 and 20. Each panel, 18 and 20, has a top edge 22, a bottom edge 24 and a pair of side edges, 26 and 28, which converge in a direction from the top edge 22 to the bottom edge 24. The liquid collection pouch 14 is formed by securing, such as seaming, fusing or gluing, the side edges, 26 and 28, and the bottom edge 24 of the panel 18 to the side edges, 26 and 28, and the bottom edge 24 of the other panel 20. By securing the side edges 26 and 28 of each panel, 18 and 20, the side walls 27 of the liquid collection pouch 14 are made continuous. By securing the bottom edges 24 of each panel, 18 and 20, the bottom end 29, defined by edges 24 of the liquid collection pouch 14, is closed. Furthermore, the top edges 22 of each panel, 18 and 20, define an opening 30.

The panels 18 and 20 may be formed from a variety of materials. Examples of these materials include low density polyethylene film of sufficient thickness, and liquid

repellent nonwovens or a combination thereof. In one embodiment, the panel 18 may be formed from a blue polyethylene film, no. CXAS 814L, a product of Edison Plastics. The panel 20 may be formed from a clear polyethylene film, no. CXAS 814F, also a product of Edison Plastic. Generally, when formed from a film material, the thickness of the film may range from about 2 mils to about 10 mils, and desirably, from about 3 mils to about 8 mils and most desirably, from about 3 mils to about 5 mils.

Referring now to FIG.s 3, 4 and 5, each panel, 18 and 20, has portions thereof between the respective top edges 22 and the respective bottom edges 24 defining an opening 32. An elastic panel 34 is secured to each panel, 18 and 20, and overlies the respective openings 32 in each panel, 18 and 20. Furthermore, each elastic panel 34 has portions defining an expandable opening 36 which is adapted for receiving a body part, such as an arm or leg. Additionally, the panel 20 is provided with a port 35 for evacuating liquids collected within the liquid collection pouch 14. A plug 37 may be inserted into or removed from the port 35 for selectively closing and opening the port 35 during the surgical procedure.

The elastic panels 34 may be formed from a variety of materials. Examples of these materials include a thin sheet or film formed from a thermoplastic, elastomeric polymer, such as for example, styrene-butadiene-styrene block co-polymer (a KRATON® polymer), styrene-ethylene/butylene-styrene block co-polymer (KRATON®G polymer), polyurethane, and co-polyether esters or co-polyesters. In one embodiment, the elastic panels 34 may be formed from a blue, 5 mil film sold by Clopay Corporation of Cincinnati, Ohio under the trademarks ELASTOFLES® K or ELASTOFLEX®II.

With particular reference to FIG. 5, a first support structure 38 is secured near the edge 22 of the panel 20 and extends a distance along and generally parallel to the edge 22. A plurality of spaced apart second support structures 40 are secured to the panel 20. The support

structures 40 extend generally vertically in a direction from the opening 30 of the liquid collection pouch 14 to the bottom edge 28 when the liquid collection pouch 14 is in an open position, as illustrated in FIG. 5. In those instances when the second support structures 40 are formed from a malleable material, the ends thereof terminating in the body of the panel 20 may be overlaid by an adhesive patch 42, such as a patch of clear adhesive tape manufactured by the 3M Company, part no. 1509.

The first and second support structures, 38 and 40, not only maintain the opening 30 of the liquid collection pouch 14 in any number of desirably fixed or stabilized positions during surgical procedures, but the first and second support structures 38 and 40 also function to maintain portions of the side wall 27 defined by the panel 20 in any number of desirably fixed or stabilized positions during the surgical procedure. When the pouch 14 is secured to the main sheet 12, the orientation of the opening 30 of the liquid collection pouch 14 and the side wall 27 defined by the panel 20 may be fixed or stabilized in any number of desirable positions by selectively manipulating, such as bending or twisting, the first and second support structures, 38 and 40, respectively.

The phrase "fixed or stabilized", with respect the combination of first and second support structures 38 and 40 and with the opening 30 and/or the side wall 27, means that the portions of the pouch 14 defined by such opening 30 and/or side wall 27 adjacent to or in contact with such support structures require the application of a greater force thereagainst to change the spacial orientation thereof as opposed to similar portions of a similar pouch without such support structures.

The first and second support structures, 38 and 40, may be formed from a variety of materials. Examples of these materials include malleable strips, malleable coated strips, malleable wire, malleable coated wire, malleable plastic and foam rods or any combination thereof. In one

embodiment, the first and second support structures, 38 and 40, are formed from coated malleable wire available from Bedford Industries of Worthington, Minnesota and known as plastic laminated tie ribbons. In one embodiment, the plastic laminated tie ribbons may be further defined as double wire, self-adhesive cut ties which are 0.315 inches wide and include a single gang of 23 gauge steel wire (two wires per gang) held within an extruded polyolefin strip. The plastic laminated tie ribbons may be made self-adhering by the securing a length of 3M 1509 tape, a product of the 3M Company, to one side of the plastic laminated tie ribbon.

Referring now to FIG. 2, a cross-sectional portion of the panel 20 take along lines 2-2 of FIG. 1 is illustrated. The second support structure 40 is secured to the outer surface 44 of the panel 20 or the surface which faces away from the main sheet 12. It will further be noted that a portion of the second support structure 40 is folded over the edge 22 and is secured to the inner surface 46 of the panel 20, or surface which faces the main sheet 12. In this way a portion of the panel 20 near the edge 22 is captured between portions of the support structure 40.

The first support structure 38, desirably a length of malleable coated wire, is secured to the inner surface 46 of the panel 20 or surface which faces the main sheet 12. More particularly, the first support structure 38 is positioned a distance from the edge 22 and overlies a portion of the second support structure 40 which is secured to the surface 46 of the panel 20. In one embodiment, when the panel 20 is formed from a polymer film, such as a polyethylene film and the first and second support structures, 38 and 40, are formed from lengths of malleable coated wire, the first and second support structures, 38 and 40, may be secured to the panel 20 with pressure sensitive tape, such as pressure sensitive tape No. 1525, a product of the 3M Company.

Referring now to FIG. 3, a cross-sectional portion of the panel 20 taken along lines 3-3 of FIG. 1 is illustrated. The elastic panel 34 is secured to the outer surface 44 of the panel 20 such that the opening 36 of the elastic panel 34 aligns with the opening 32 of the panel 20. The elastic panel 34 may be secured to the panel 20 by heat sealing or sonic bonding.

Referring now to FIG. 4, a cross-sectional portion of the panel 18 and the main sheet 12 taken along lines 3-3 of FIG. 1 is illustrated. The elastic panel 34 is secured to the outer surface 48 of the panel 18 such that the opening 36 of the elastic panel 34 aligns with the opening 32 of the panel 18. The elastic panel 34 may be secured to the panel 18 by heat sealing or sonic bonding.

The panel 18 is secured to the main sheet 12 by securing the inner surface 50 of the panel 18 to the outer surface 52 of the main sheet 12 such that the opening 32 of the panel 18 aligns with the opening 13 of the main sheet 12. When the panel 18 is formed from a polymer film, such as polyethylene film, and the outer surface of the main sheet 12 is formed from a spunbond web, the panel 18 may be secured to the main sheet 12 by a hot melt adhesive or a pressure sensitive tape.

While the invention has been described in detail with respect to specific embodiments thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of and equivalents to these embodiments. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.

We claim:

1. A liquid collection pouch comprising:  
side walls closed at one end and another end thereof  
defining an opening; and  
wherein portions of the side walls are stabilized.
2. The liquid collection pouch of claim 1 wherein portions  
thereof defining the opening are stabilized.
3. The liquid collection pouch of claim 1 wherein a  
portion of the side walls defines a wall opening and  
wherein an elastic panel is secured the side walls and  
overlies the wall opening.
4. The liquid collection pouch of claim 1 further defined  
as being generally triangular in shape.
5. A liquid collection pouch comprising:  
continuous side walls closed at one end and another end  
thereof defining a liquid collection pouch opening;  
a generally laterally oriented support structure  
secured adjacent portions of the side walls defining the  
opening and; and  
a generally vertically oriented support structure  
secured to a portion of the side walls.
6. The liquid collection pouch of claim 5 wherein the  
first support structure overlies a portion of the second  
support structure.
7. The liquid collection pouch of claim 5 wherein one of  
the side walls has portions defining a wall opening and  
wherein an elastic panel is secured to said portions of the  
side wall such that the elastic panel overlies the wall  
opening.

8. The liquid collection pouch of claim 5 further defined as being generally triangular in shape.

9. A surgical drape comprising:

a main sheet;

a liquid collection pouch secured to the main sheet, wherein the liquid collection pouch comprises;

5 continuous side walls closed at one end and another end thereof defining a liquid collection pouch opening;

a generally laterally oriented support structure secured adjacent portions of the side walls  
10 defining the opening;

a generally vertically oriented support structure secured to a portion of the side walls;  
and

15 wherein one of the side walls has portions defining a wall opening and wherein an elastic panel is secured to said portions of the side wall such that the elastic panel overlies the wall opening.

10. The surgical drape of claim 9 wherein the liquid collection pouch is generally triangular in shape.

11. The surgical drape of claim 9 wherein a portion of the side walls of the liquid collection pouch is secured to the main sheet of the drape.

12. The surgical drape of claim 9 wherein a patch, secured to the side wall, overlies an end of the generally vertically oriented support structure.



13. A surgical drape comprising:

a main sheet having portions defining an opening;

a liquid collection pouch comprising;

5 a pair of juxtaposed panels, wherein each panel has a top edge, a bottom edge and a side edges which converge from the top edge to the bottom edge and wherein the panels are secured together along the side edges and the bottom edge and wherein the top edges define a liquid collection pouch opening;

10 wherein each panel has portions thereof between the top edge and the bottom edge defining a opening and wherein an elastic panel is secured to each panel such that the elastic panel overlies said opening, and wherein each elastic panel has portions defining an expandable opening  
15 adapted for receiving a body part;

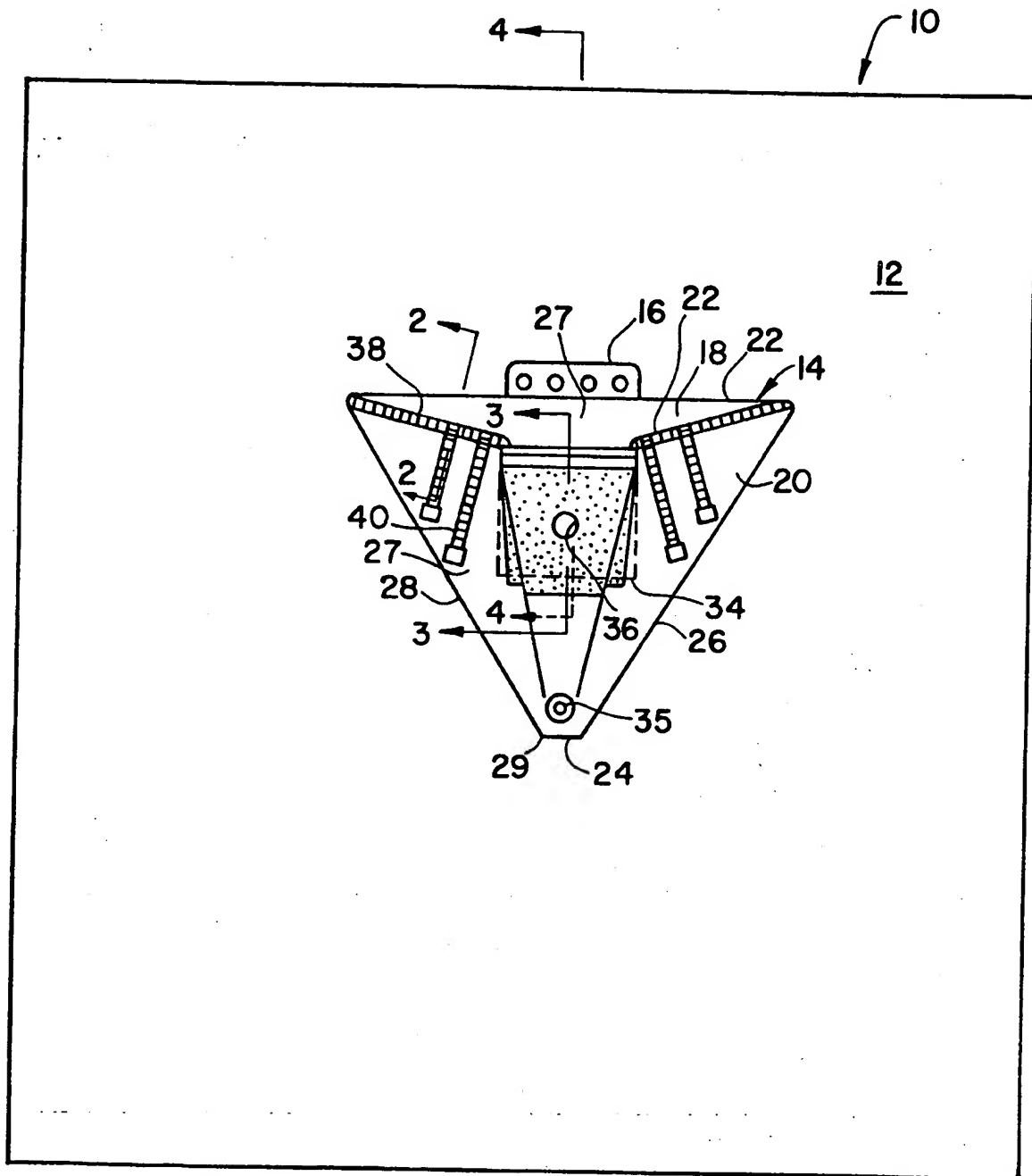
a first length of malleable coated wire secured adjacent the top edge of one of the panels;

a plurality of spaced apart lengths of malleable coated wire secured to the panel to which the first length of  
20 malleable coated wire is secured, wherein said plurality of spaced apart lengths of malleable coated wire extend generally vertically along said panel when the pouch is in an open position; and

wherein the other panel is secured to the main sheet  
25 such that the expandable opening of said elastic panel of said panel aligns with the opening in the main sheet.

14. The surgical drape of claim 13 wherein a patch, secured to the panel, overlies one end of each of the spaced apart lengths of malleable coated wire.

1/3



2/3

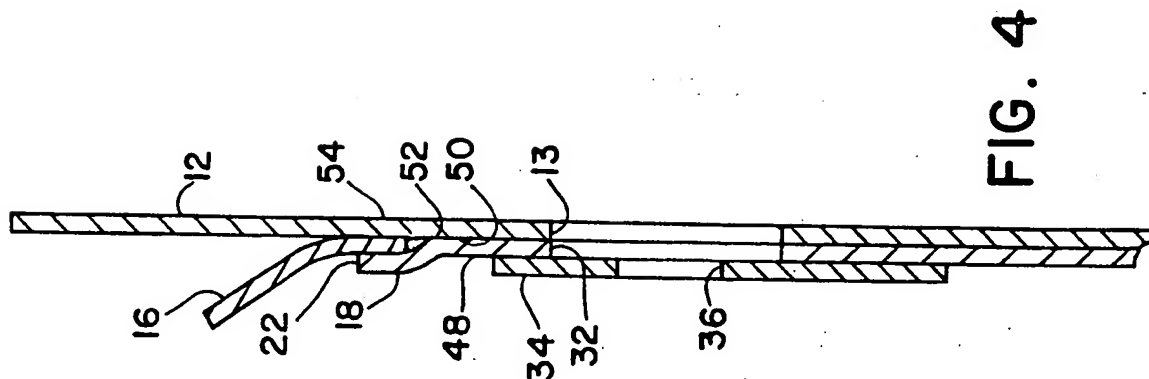


FIG. 4

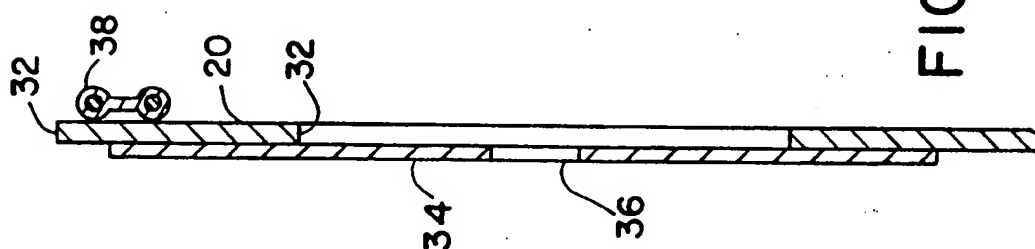


FIG. 3

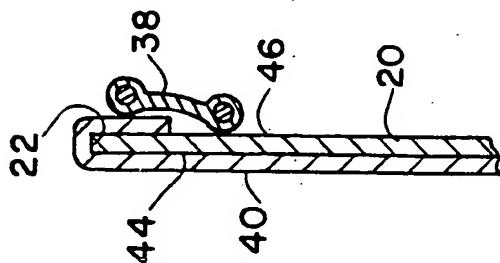


FIG. 2

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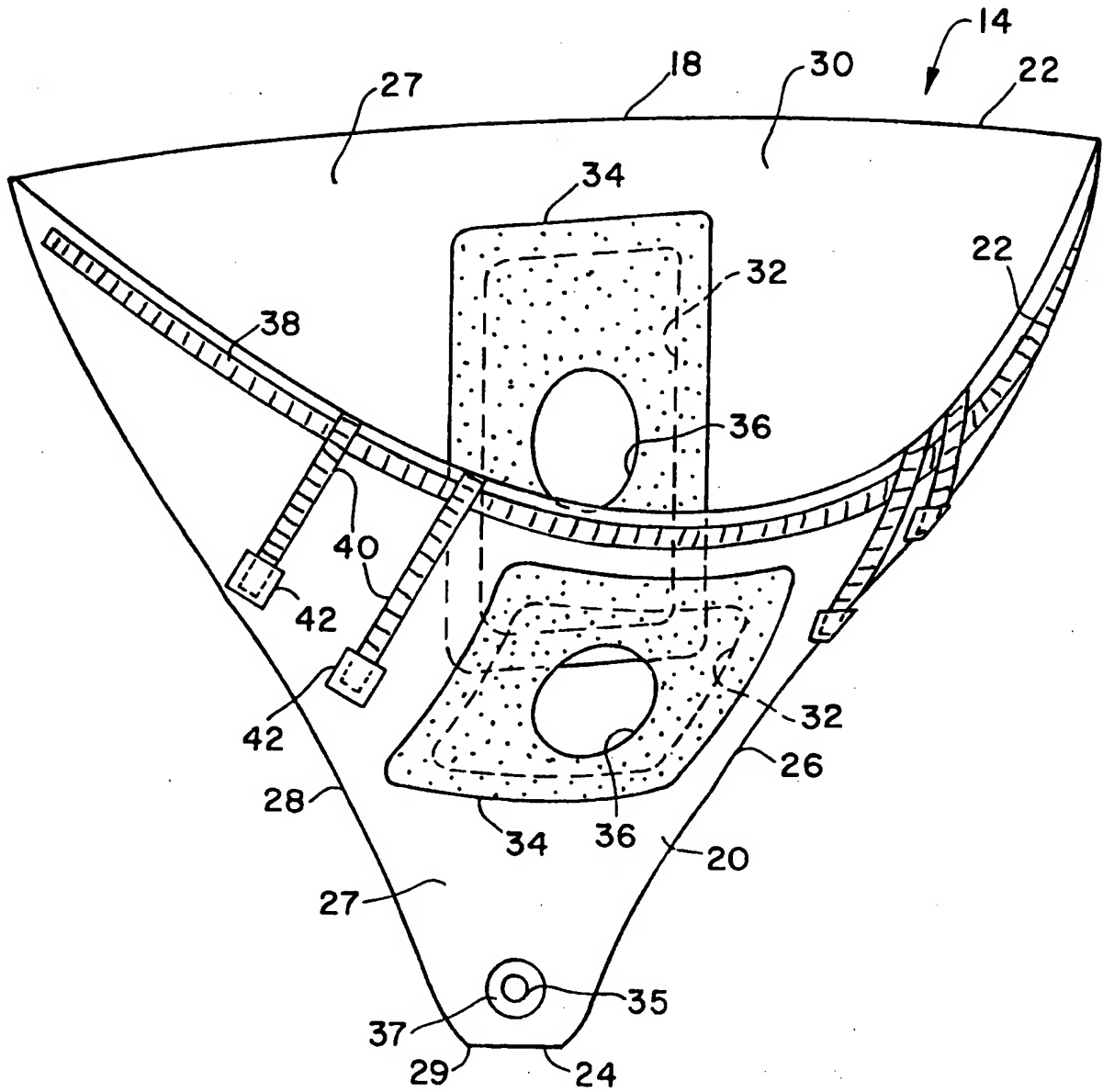


FIG. 5

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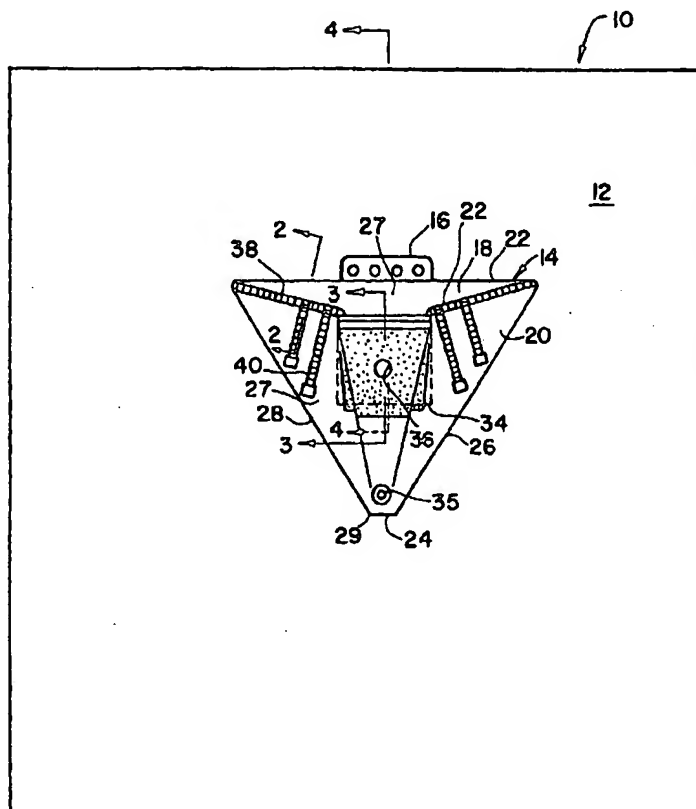
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[Continued on next page]

(54) Title: SURGICAL DRAPE AND METHOD OF ASSEMBLY



(57) Abstract: A surgical drape having a liquid collection pouch is provided. The liquid collection pouch includes support structures secured thereto along and boarding the mouth of the liquid collection pouch and along the side walls of the liquid collection pouch. Examples of the support structures include malleable strips, malleable coated strips, malleable wire, malleable coated wire, plastic and foam rods or any combination thereof.

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## INTERNATIONAL SEARCH REPORT

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## A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 002 069 A (THOMPSON JOSEPH F ET AL) 26 March 1991 (1991-03-26) column 3, line 44 - line 46 column 4, line 11 - line 14 column 4, line 63 - column 5, line 2 column 5, line 25 - line 27; figures 1,4,7A,7B	1-5,8-15
A	---	7
X	US 5 107 859 A (ALCORN DENNIS R ET AL) 28 April 1992 (1992-04-28) column 5, line 43 - line 55; figure 5	1-4
P,X	US 5 494 050 A (REYES ROGELIO) 27 February 1996 (1996-02-27) column 4, line 53 - column 5, line 29; figures 1,2,7,9A,12 --- -/--	1-4



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Date of the actual completion of the international search

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## INTERNATIONAL SEARCH REPORT

International Application No  
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